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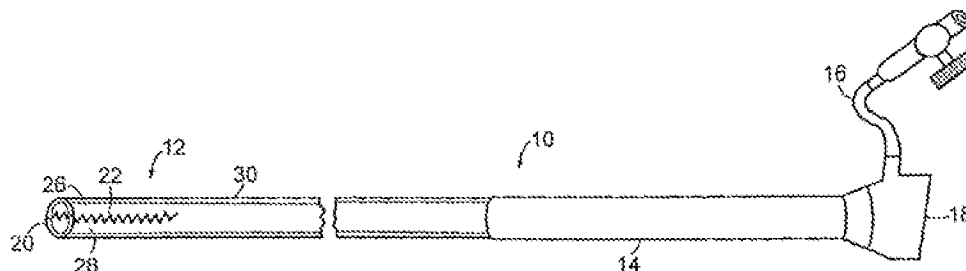
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(54) Title: EXPANDABLE SHEATH TUBING



(57) Abstract: An expandable catheter accommodates a medical device that is being removed from a body with a larger diameter than the catheter. The same catheter may be used to reposition a device within the body to an alternative delivery site. A catheter or sheath may be used to deliver a medical device, surgical instrument, or biological sample.

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## EXPANDABLE SHEATH TUBING

### CROSS-REFERENCE TO RELATED APPLICATION

This application claims priority to provisional application serial no. 60/496,168, filed August 19, 2003, which is expressly incorporated by reference.

### BACKGROUND

[0001] The inventions relate to a sheath or catheter that has an expandable distal end.

[0002] In many minimally invasive medical procedures, an introducer sheath or catheter may be placed in a vessel to gain access to a site within a body for a diagnostic or therapeutic procedure. Sheaths and catheters are used as conduits to pass surgical instruments, implantable devices, or biological matter, such as clots, tissue samples, or other matter. The inner diameter of the sheath is designed as large as possible for the surgical instrument, implant device, or tissue sample to pass through it. It is generally desirable to minimize the outer diameter of the sheath and maximize the inner diameter of the sheath. A small outer diameter is desired to minimize the size of the hole at the insertion site. A smaller outer diameter also provides less disruption to the circulatory pathway. Since the outer diameter may be minimized and the inner diameter may be maximized, the thickness of the wall of the sheath could lack sufficient column strength for insertion into a blood vessel or other circumstances with longitudinally applied forces.

[0003] Medical devices that are implanted may require removal from the body or repositioning within the body. The device that is to be removed may be a temporary implant which has performed the desired diagnostic or therapeutic function.

Alternatively, a device may be classified as a permanent implant but may require removal

for some other reason. Sometimes devices need to be repositioned in the body. One way of repositioning a device is to pull the device back into a catheter (or push the catheter around the device) so that the device is disposed within the catheter. Then the device is repositioned to a desired delivery location and then deployed. The devices that are removed or repositioned may not collapse into a reduced profile configuration easily or completely.

[0004] Because the devices may not collapse completely or in a suitable orientation it may be difficult to reconstrain the device in a catheter. Specifically, this difficulty may be compounded by the material that is used to construct the catheter. The catheter walls are optimally designed to be as thin as possible while having sufficient column strength for proper operation. A material commonly selected for the construction of catheters typically has high stiffness or rigidity. The same material properties that are desirable in the construction of the catheter may make the withdrawal of an implant or tissue more difficult because a catheter constructed of a stiff material will not expand to accommodate a device that is being reconstrained after deployment. This can make it awkward to pass surgical instruments, implantable devices, and tissue samples either in or out of the sheath tip.

#### SUMMARY

[0005] It is desirable to have a catheter that is suitable for reconstraining large or awkwardly shaped surgical instruments and implantable devices after delivery such that they may be repositioned or removed from the body, including medical devices that are being removed from a body with a larger diameter than that of the catheter. The same catheter may be used to reposition a device within the body to an alternative delivery site. A catheter or sheath constructed according to this description may be used to deliver a

medical device, surgical instrument, or biological sample. These catheters have a reduced risk of splitting or tearing when a device is positioned within the catheter. As used here, the terms sheath and catheter are used interchangeably.

[0006] According to one embodiment, a distal tip of a catheter is constructed to expand radially and thus facilitate the retrieval and repositioning of surgical tools, implantable devices, or biological matter that have a larger diameter than the unexpanded diameter of the catheter. The distal end of the catheter may be formed with either a single layer or multiple layers of material which may be the same or different from the materials comprising the rest of the catheter. In one embodiment, the distal end of the catheter may have one or more straight or curved generally longitudinally-oriented slits. The slits extend through the thickness of one or more layers of the catheter. During delivery of a device, the slits may be closed or open depending on desired delivery characteristics. If the device requires removal or repositioning, the slits in the catheter separate and the catheter diameter expands if necessary as the device is retrieved into the catheter. An elastomeric layer holds the sliced portions of the catheter together and provides an expandable layer so that the catheter remains a single piece. The slits may extend longitudinally from the distal end to a location up to 15 cm along the length of the catheter or more. Alternatively, the slits may begin at a location slightly away from the distal end and continue longitudinally for up to 15 cm along the catheter or more.

[0007] In another embodiment, one or more zig-zag slits may be provided longitudinally along a length of the distal end of the catheter and in a direction perpendicular to the radial axis of the catheter, or it can have some angle relative to a perpendicular orientation, or they can have an overall curved shape. The zig-zag configuration of the slits may include straight cuts or separations in the catheter. The zig-

zag cuts also may be rounded at the peak and/or the valley of the cut, and/or along the length of the cut. In a preferred form, the size of the zig-zag slits are constructed so that in an expanded configuration (e.g., when a device has been retrieved) the teeth of opposing sides of the zig-zag do not completely separate. Thus the catheter minimizes the likelihood of a longitudinal tear of the elastomeric material, if present. It is desirable that the entire device that has been inserted into the catheter remain in the catheter and not extend through any perforations or tears in the catheter.

[0008] The formations described above may be used together and other formations may be used to allow for radial expansion of the catheter as the device is being positioned within the catheter. These formations may or may not require longitudinal contraction. These formations can be present along a portion or the entire length of the sheath tip. Other materials can be added to the sheath tip, such as wires for strength, coatings to change friction characteristics, and coatings of a different durometer, or, the device can be made to have a minimal number of parts and portions.

[0009] The catheter can be an introducer through which surgical instruments and implantable devices such as stents, filters, occluders, or other devices are inserted into a living body. The catheter can also be a retriever through which tissue or other biological matter, surgical instruments, and implantable devices are withdrawn from a living body. The cut of the catheter material that forms the slits may be aligned with the radial axis or may be slanted or curved. The cut may be formed from a sharp object, such as a knife, or alternative methods may be used to form the slits.

[0010] In another embodiment, the catheter or sheath may have a distal end that is partially or wholly comprised of braided material. In such a device that uses a braided configuration, the longitudinal length shortens as the radius expands. This embodiment

has the advantage that individual segments of the catheter are not separated as the catheter expands radially.

[0011] A radially expandable distal end of a catheter allows surgical instruments, biological matter, and implantable devices, including such devices as may be folded, compressed, or loaded in the sheath in a specialized manner such that the device can be introduced through a smaller diameter delivery sheath than otherwise possible, to be more easily deployed upon delivery to the desired site within the body. A radially expandable distal end of a catheter allows and facilitates retrieval of surgical instruments and implantable devices, including devices that unfold or expand or otherwise deploy in some way after delivery within the body. The expandable distal end can accommodate more easily the volume of a partially or wholly deployed device, and can overcome snags resulting from the geometry of a partially or wholly deployed device, reducing trauma to the vessel through which such instruments or implantable devices must be withdrawn. Once a device is retrieved into the catheter, the sheath tip can further aid in the complete recovery of a device by acting to compress the device. It is desirable that an expandable distal end of a catheter accommodates an article with a larger dimension than that of the catheter.

[0012] These and other features and advantages will become apparent from the drawings and detailed description.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0013] The inventions will be more clearly understood by reference to the following detailed description when considered in conjunction with the accompanying drawings, wherein:

[0014] FIG. 1 is an overall view of a catheter constructed according to an embodiment;

[0015] FIG. 2(a) is a side perspective view of a catheter according to an embodiment of the present invention with a portion of an outer elastomeric layer removed;

[0016] FIG. 2(b) is an end view section taken from lines 2(b)-2(b) in FIG. 2(a);

[0017] FIG. 2(c) is a side perspective view of a catheter according to an embodiment with a portion of an outer elastomeric layer removed;

[0018] FIG. 2(d) is an end view section taken from lines 2(d)-2(d) in FIG. 2(c);

[0019] FIG. 2(e) is a detail view of a catheter constructed according to an embodiment illustrating a possible configuration with a device disposed in the distal end of the catheter and a clear elastomeric material used as an outer layer;

[0020] FIG. 2(f) is a detail view of the tooth configuration taken from circle 2(f) in FIG. 2(e);

[0021] FIGS. 3(a), 3(c), 3(e) and 3(g) are detailed views of alternative embodiments of the distal end of a catheter;

[0022] FIGS. 3(b), 3(d), 3(f) and 3(h) are end views of the detail views of FIGS. 3(a), 3(c), 3(e) and 3(g), respectively with the entire outer elastomeric sleeve removed for clarity;

[0023] FIGS. 4(a) and 4(b) illustrate slices or cuts at various orientations;

[0024] **FIGS. 5(a) and 5(b)** are detailed views of an alternative embodiment of the distal end of the catheter using a braid.

#### DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0025] A catheter can expand radially at its distal end to accommodate an element (e.g., medical device) that is larger than the diameter of the catheter. At times it is desirable, sometimes necessary, to remove or reposition a medical device that has been previously deployed. A catheter as described here allows a device to be removed or repositioned by expanding to accommodate the device as the device is brought within the catheter. According to some embodiments, the catheter is configured to reduce the possibility of tearing the elastomeric layer longitudinally along the catheter by the edges of a surgical instrument or implantable device being removed or repositioned.

[0026] Referring to the drawings, wherein like reference numerals designate identical or corresponding parts throughout the several views, and more particularly to **FIG. 1** thereof, a catheter **10** is illustrated with a distal end portion **12**. The catheter according to this embodiment is adapted to be introduced into the vasculature in a normal procedure as known to those skilled in the art. The expandable distal end portion **12** can expand radially when something having a larger diameter than its normal diameter is introduced into the distal end. The catheter **10** includes a hub portion **14** and side tube **16** which leads into the hub portion **14**. A medical instrument or implantable device to be inserted into a patient is placed through a proximal end **18** and is intended to exit the catheter **10** at a distal end **20**. When the catheter **10** is used to remove or reposition an implantable device the device enters the catheter at the distal end **20**. The implantable device placed, removed or repositioned through the catheter **10** may be a medical device, including, e.g., stents, filters, occluders, or other devices, or a delivery element to deliver



a medical device, including stents, filters, occluders, or other devices, into a patient's body.

[0027] The catheter **10** can be various lengths, such as between 50 cm and 100 cm. The catheter can be longer or shorter as necessary for a particular application. The diameter of the catheter is typically between 5 and 15 French. Of course, the catheter could have a larger or smaller diameter as a particular application warranted. Typical wall thickness of the catheter **10** can vary greatly depending on the material selected and the length of the catheter.

[0028] As illustrated in **FIG. 1**, the distal end **20** of the catheter **10** is expandable because of zig-zag shaped slit **22** disposed on the distal end of the catheter. A second zig-zag slit (not viewable) is disposed on the other side of the circumference of the catheter. The zig-zag slits create two catheter portions **26** and **28** with a generally semi-circular cross-section along the length of the zig-zag slits. A third zig-zag slit can also be provided to divide the circumference into three sections, and further slits could be provided. In each case, the slits can be centered equally spaced around the circumference, e.g., every 120 degrees for three slits, or they can be spaced at unequal intervals, e.g., at 90 to 180 degrees for three slits. As described in more detail below, when a device is introduced into the distal end of the catheter to be removed or repositioned, the slits allow the catheter portions **26** and **28** to separate to accommodate the device. A clear (as illustrated) elastomeric layer **30** is on the outside of the catheter and enables the catheter to have the required structural integrity.

[0029] The elastomeric layer may be disposed on the inside surface of the catheter or on the outside surface of the catheter or both. The layers of the catheter are bonded together, such as through heat bonding, adhesives, or other suitable methods to join the

two or more layers. If the elastomeric layer is disposed on the outer surface of the catheter a heat shrink tube may be used. Although the thickness of the layer may vary depending on the needs of a particular application and the material selected, the thickness may be between about 0.001 and 0.025 inches (25 to 625 microns), preferably between about 0.002 and 0.008 inches (50 to 200 microns). Materials for the elastomeric outer cover may include silicone, polyurethane, or polyether-amide block copolymer, such as a material known as Pebax. The elastomeric layer(s) allows the catheter portions 26 and 28 to expand as much as needed to recapture or reposition the device. The elastomeric outer cover can be flush with an inner wall at the distal end of the catheter, or the outer cover can extend beyond the inner wall a short distance to create an overhang that provides a less stiff and "softer" end. This softer tip can help to guide a divide that may have coils or other structures that could get caught if brought back into contact with a stiffer conduit. This overhang would typically have a length of about 0.005 to 0.5 inches (0.125 to 12.5 mm) and preferably about 0.1 inches (2.5 mm), and a thickness of about 0.005 to 0.1 inches (.125 to 2.5 mm), and preferably about 0.02 to 0.04 inches (0.5 to 1.0 mm). In addition to the end portion, other sections of the catheter can include multiple layers as shown, for example, in application serial no. 10/693,398, which is incorporated herein by reference.

[0030] **FIGS. 2(a) and 2(b)** illustrate a distal end portion 40 of a catheter. The illustrated embodiment includes a two-wall structure comprised of an elastomeric cover 30 surrounding a relatively high stiffness inner wall 42 (compared to the stiffness of the outer wall). The inner wall has two slits 44, 46 extending in a zig-zag pattern along a longitudinal direction at the distal end of the catheter. The material for the inner wall may include high density polyethylene (HDPE), high-stiffness polyether-amide block copolymer or, high stiffness polyurethane. The zig-zag pattern may extend

longitudinally up to 15 cm or more along the length of the distal end portion 40 of the catheter.

[0031] The zig-zag pattern forms tooth shapes 52 along the length of the zig-zag pattern. The shapes may be triangular as shown or, alternatively, rectangular, semi-circular or irregular. As depicted in FIG. 2(a), zig-zag slits of the inner wall preferably result in teeth with acute angles and teeth of height equal to one-quarter of the circumference, although the height could vary. Tooth geometry may be variable along the length of the distal end portion 40 of the catheter. For example, larger teeth may be provided at the distal end of the catheter and smaller teeth may be provided towards the proximal end. The geometry of the teeth may change along the length of the slit such that the leading edge of the tooth has an angle to provide a more longitudinal profile. Thus, teeth sizes, widths or shape may change along the length of the tube tip or may change into one of the various slits types discussed below. Of course, more than two longitudinally extending zig-zag slits may be formed at the distal end portion 40 of the catheter. If more than two slits are created, the spacing may be equal along the circumference of a cross-section or, alternatively, the spacing can vary. Varied spacing of the slits may be helpful if a device has an irregular geometry.

[0032] FIGS. 2(c) and 2(d) illustrate the distal end portion 40 of the catheter in a slightly expanded configuration. The catheter 26, 28 portions with semicircular cross-sections are slightly spread apart and allow for a device with a larger diameter to be inserted into the catheter than would be able to absent the longitudinal slits. The elastomeric layer 30 shown partially removed in FIG. 2(c). FIG. 2(d) illustrates the stretching of the elastomeric layer when the catheter portions 26 and 28 are separated. The slits provide additional flexibility of the inner wall to facilitate expansion, while

maintaining longitudinal or column stiffness to inhibit buckling. In the preferred embodiment, the inner and outer layers are bonded in a manner that allows slippage at the teeth edge of the inner layer so that the stress of expansion is distributed to a larger portion of the elastomeric cover.

[0033] Referring to **FIGS. 2(e) and 2(f)**, when introducing a device into the catheter after it has been deployed there is a possibility that a portion of the device may have an edge that is sharp enough to tear the elastomeric material as the device is brought into the catheter. The configuration of the teeth that extend in a zig-zag pattern is designed to prevent puncture or tearing of the elastomeric cover. That is, the teeth are designed to be long enough to overlap as much as possible during the introduction of the device. As illustrated in **FIG. 2(f)**, it may be advantageous to extend the elastomeric material beyond the distal end of the stiffer layer. This extension assists in the retrieval of the device by guiding or "funneling" the device into the catheter. The extension may be approximately 0.10 in (0.25 cm). Of course, shorter or longer extensions may be used depending on specific situations. As illustrated in **FIG. 2(f)**, the overlap of the teeth 52 by the distance designated by reference numeral 56 minimizes the possibility that a sharp edge of a device will tear the elastomeric layer as it is drawn into the catheter. Of course, the teeth may be constructed so that they separate sufficiently when a device is introduced into the catheter so that the distance 56 may be reduced to zero. It is also contemplated that the teeth may be designed not to overlap when an object with a much larger diameter is introduced into the catheter. The overlapping ends of the teeth are helpful to make sure that the elastomeric layer is not torn by any sharp edge.

[0034] **FIGS. 3(a) through 3(h)** illustrate other aspects that may be incorporated into catheters described here. For clarity of illustration, the elastomeric layer has not been

illustrated, but may or may not be present. Specifically, **FIGS. 3(a)** and **3(b)** show the distal end portion **60** with four slits **62**, **64**, **66**, and **68** disposed longitudinally along a length of the distal end. The length of the slits may be up to 15 cm or more. The slits create catheter quarter sections **72**, **74**, **76** and **78** which separate and contain a device within the distal end. As illustrated in **FIG. 3(b)**, the slits may extend in a direction radial to the center **70** of the cross-section of the tube. This is a simple, easy to create geometry. **FIGS. 3(c)** and **3(d)** illustrate an alternative geometry for the slit. Specifically, a distal end portion **80** may be provided with two slits **82** and **84** that are oriented at an angle such that they do not intersect the center **86** of a cross section of the catheter end portion **80**. Slots of this configuration may assist in keeping the elastomeric layer bonded to the high durometer (inner) layer of the catheter, or, when still overlapped, minimize tearing of the elastomeric layer, if present. **FIGS. 3(e)** and **3(f)** are still other alternative embodiments. As illustrated a distal end portion **90** has two slits **92** and **94** that extend from the distal end of the catheter. The slits **92** and **94** are curved or wavy along the length. The curved slits are relatively easy to construct and may provide advantages over the straight slits by reducing the possibility that sharp edges of a device would tear the elastomeric layer and otherwise facilitating delivery or recovery of an instrument or device. **FIGS. 3(g)** and **3(h)** illustrate still further another embodiment. Here, a distal end portion **100** includes helical slits **102**, **104** and **106**.

[0035] **FIGS. 4(a)** and **4(b)** illustrate the end view of a catheter having alternative configurations for the orientation of the slits that may be used to create any of the slits previously mentioned. **FIG. 4(a)** has two slits **110** and **112** that are oriented in a manner shown. Similarly, **FIG. 4(b)** illustrates four slits **120**, **122**, **124**, and **126** that are cut into the catheter in the manner illustrated. Each of these slit configurations can be varied by

the number of slits in the catheter and the orientation of the slit. The slit configurations can be applied to each of the embodiments described above.

[0036] In another embodiment, the expandable catheter end portion 130 includes a wall 132 formed by braided material 134 as illustrated in FIGS. 5(a) and 5(b). The braid 134 has one or more threads of high-stiffness material knitted or woven together. Braid 134 can be obtained commercially from Techflex, Inc. of Sparta, New Jersey. In this embodiment, the braided distal end may be approximately the same size as or smaller than the rest of the sheath tube. Braided material has the advantage of readily expanding in the radial direction. This advantage is used to accommodate the introduction of a device into the distal end of the catheter. As the catheter radially expands to accommodate a device, the braided material contracts longitudinally, i.e. axially, as depicted in FIG. 5(b). Longitudinal compression of the distal end of the catheter may be achieved by the positive force of the tissue sample, surgical instrument, or implant device being withdrawn into the sheath tip. Alternatively, the longitudinal contraction of the distal end of the catheter may be produced by the positive action of a control rod or contraction cable. The braided expandable distal end of the catheter illustrated in FIG. 5(a) and 5(b) may or may not include an elastomeric outer cover.

[0038] Features of the embodiments described here include the following: the expandable sheath tip facilitates the deployment and retrieval of surgical instruments, implantable devices, and biological matter; use of the expandable sheath tip to partially deploy, expand or inflate an implantable device or surgical instrument before delivery of such implantable device or surgical instrument is specifically envisioned. The sheath tip radially expands to more easily accommodate implantable device or surgical instrument volumes and overcome any device or instrument geometry that may tear an elastomeric

sleeve. The sheath tip may or may not be accompanied or enhanced by the addition of other materials such as braids, different tubing, or coatings. The elastomeric material, when present, expands such that the implant will be fully or partially encapsulated within the tip. The elastomeric material, when present, also serves to ensure a controlled and consistent expansion of the tip geometry. In addition to the containment of the retrieved device and protection against cut sheath tip areas, the elastomeric material, when present, may extend past the tip of the sheath to form a highly flexible ring that corrects snags, ensuring the successful entry of the device into the sheath tip.

[0039] Once the device is retrieved, the material continues to aid in the complete recovery by compressing the implant to facilitate any remaining size discrepancy between the retrieved device and the dimensions of the full length of the sheath. The expandable sheath tip preserves rigidity, column strength, and stiffness where necessary.

[0040] In other configurations of catheters, combinations of the above embodiments are possible. For example, one embodiment includes a high-durometer inner wall with a longitudinally-oriented zig-zag slit, having a cover comprised of a low-durometer braided material. Additionally, the slits may extend the entire length of the catheter so that a device may be pulled through the length of the catheter. Numerous modifications and variations of the present inventions are possible in light of the above teachings. Although the embodiments have been described in detail for the purpose of illustration, it is understood that such detail is solely for that purpose, and variations can be made by those skilled in the art without departing from the spirit and scope of the inventions.

What is claimed is:

1. A catheter sheath for retrieving an object in a body, comprising:
  - an expandable distal end, the expandable distal end being a tube of one or more layers that includes at least one slit that extends throughout at least one layer of the tube, wherein a portion of one of the at least one slit being is not generally parallel to the longitudinal axis of the tube;
  - a proximal end including a port for the passage of objects into the catheter sheath;
  - and
  - a tubular percutaneous delivery component located between the proximal and distal ends that creates an uninterrupted conduit between the expandable distal end and the proximal end.
2. The catheter sheath according to claim 1, wherein the at least one slit spirals around the distal end at least one-eighth of a turn.
3. The catheter sheath according to claim 1, wherein the at least one slit is of zig-zag form.
4. The catheter sheath according to claim 3, wherein expandable distal end is a tube of at least two layers including an inner layer and an outer layer, the inner layer including at least two slits, the at least two slits being generally longitudinally oriented, the at least two slits of a zig-zag cut that forms teeth, and the outer layer does not have slits.
5. The catheter sheath according to claim 4, wherein the outer layer is elastomeric and bonded to the inner layer.
6. The catheter sheath according to claim 4, wherein the outer layer is constructed of materials is selected from the group consisting of silicone, polyurethane, and polyether-amide block copolymer.
7. The catheter sheath according to claim 4, wherein the outer layer is elastomeric and has a thickness in the range of about 0.002 to about 0.008 inches.



8. The catheter sheath according to claim 4, wherein the teeth are triangular shaped.
9. The catheter sheath according to claim 4, wherein the teeth are semi-circular shaped.
10. The catheter sheath according to claim 4, wherein the outer layer is elastomeric and insures during expansion of the expandable distal end that the teeth remain at least partially interlocked.
11. A catheter sheath for delivery and retrieval of objects during medical procedures, comprising:
  - a percutaneous shaft component; and
  - an expandable distal end of at least one layer attached to the end of the percutaneous shaft component, including a braided layer constructed of braided material that expands axially when a portion of the expandable distal end is contracted longitudinally.
12. The catheter sheath according to claim 11, wherein the expandable distal end includes a slit layer inside the braided layer, the slit layer including at least two slits, the at least two slits being generally longitudinally oriented.
13. The catheter sheath according to claim 12, wherein the braided material is of a relatively low stiffness material and the slit layer of a relatively high stiffness material.
14. The catheter sheath according to claim 11, further comprising:
  - a control element that controls the diameter of the expandable distal end by adapting the longitudinal contraction of said portion.
15. A method of recovery of an object in a biological vas, comprising:
  - introducing of a percutaneous catheter sheath, the catheter sheath including a proximal end, an expandable distal end, and a tubular percutaneous component, the

proximal end including a port for the passage of objects in the catheter sheath, the tubular percutaneous component located between the proximal and distal ends that creates an uninterrupted conduit between the expandable distal end and the proximal end, and the expandable distal end being a tube of one or more layers that includes at least one slit that extends throughout at least one layer of the tube, wherein a portion of one of the at least one slit being is not generally parallel to the longitudinal axis of the tube; and

recovering the object in the biological vas at least partially into the expandable distal end while causing the expandable distal end to partially expand.

16. The method of recovery according to claim 15, further comprising:

redeploying the object in the biological vas after recovering the object at least partially into the expandable distal end.

17. The method of recovery according to claim 15, wherein the expandable distal end is a tube of at least two layers including an inner layer and an outer layer, the inner layer including at least two slits, the at least two slits being generally longitudinally oriented, the at least two slits of a zig-zag cut that forms teeth that interlock, and the outer layer is an elastomeric material that does not have slits and which is bonded to the inner layer, the method further comprising:

ensuring that the teeth remain at least partially interlocked during expansion of the expandable distal end during manipulation of the object in the biological vas.

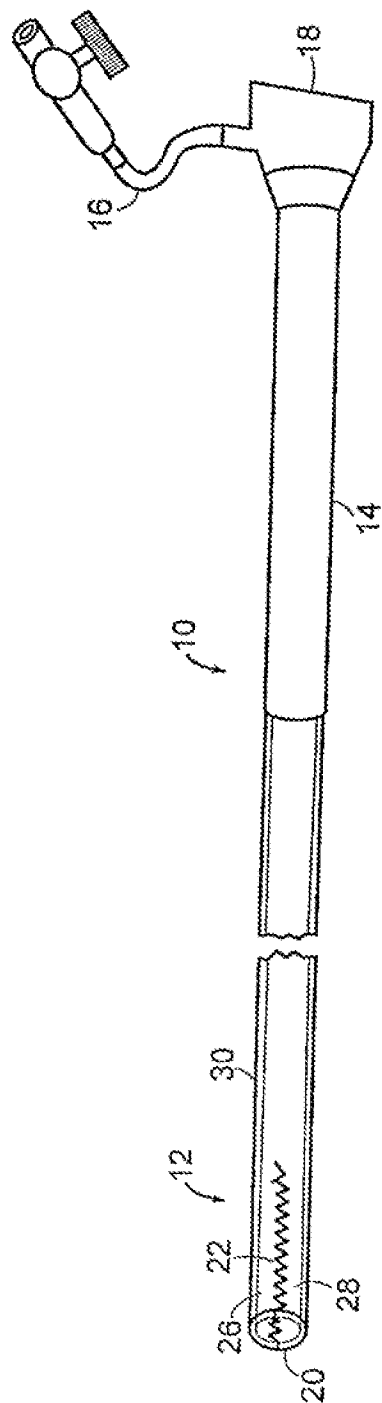
18. The method of recovery according to claim 17, further comprising:

redeploying the object in the biological vas after recovering the object at least partially into the expandable distal end.

19. A catheter sheath according to claim 1, wherein the distal end has at least a first inner layer and a second outer layer, the outer layer being made of a material that is less stiff than the material used to make the first layer, the second layer extending past the first layer at the distal end.

20. A catheter sheath according to claim 19, wherein the second layer extends past the first layer by a distance of 0.005 to 0.5 inches.
21. The catheter sheath according to claim 4, wherein the outer layer is elastomeric and wherein the teeth separate and do not remain at least partially interlocked.

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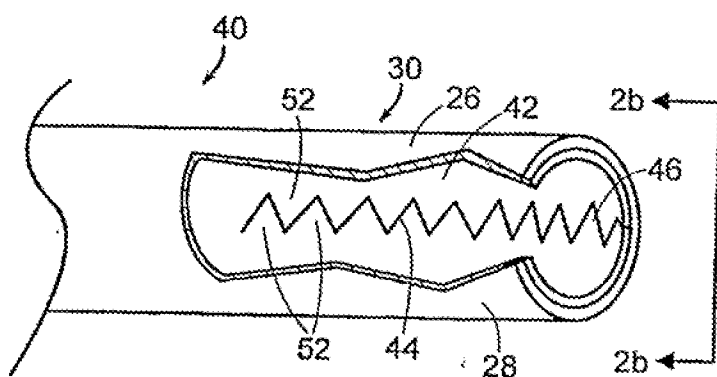


FIG. 2a

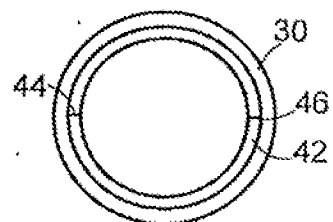


FIG. 2b

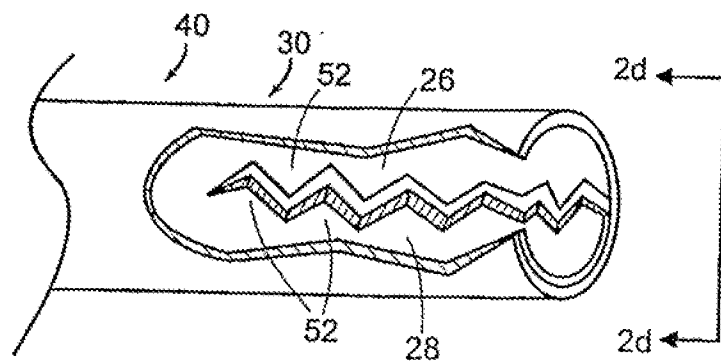


FIG. 2c

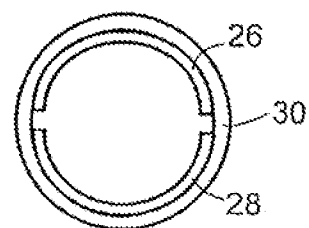


FIG. 2d

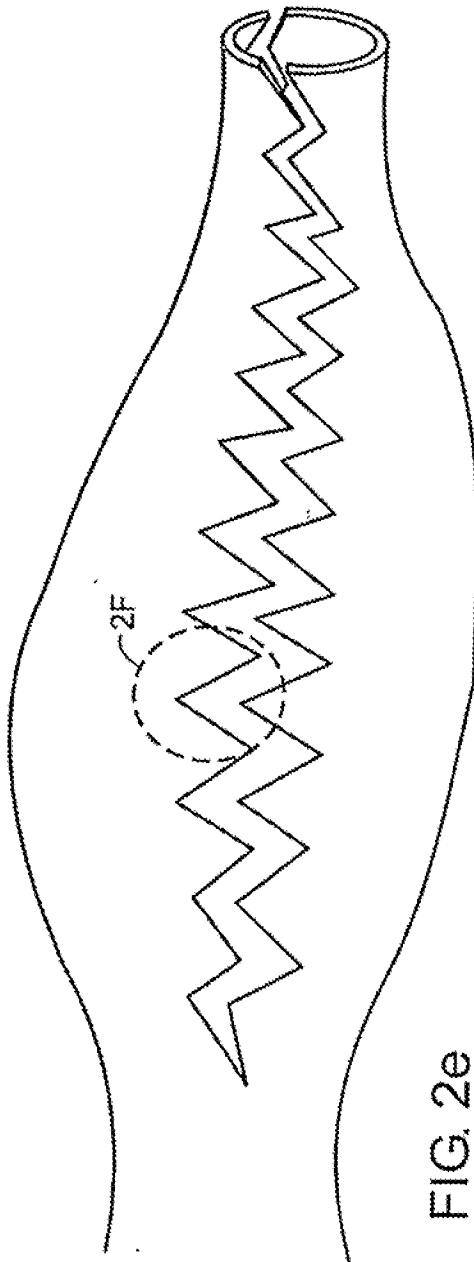


FIG. 2e

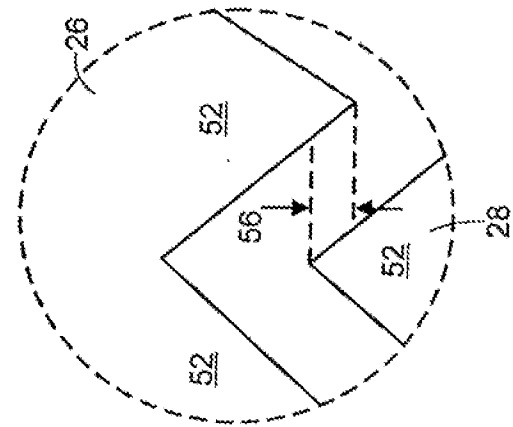


FIG. 2f

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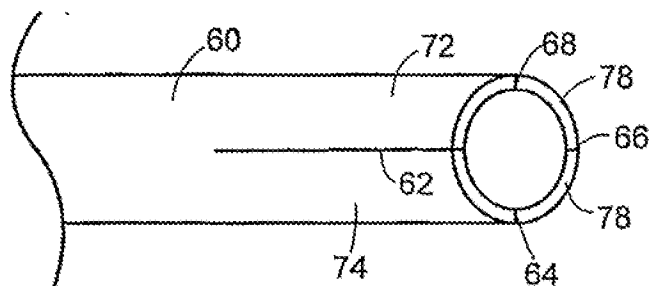


FIG. 3a

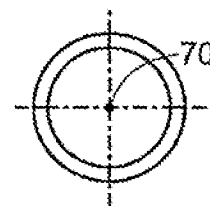


FIG. 3b

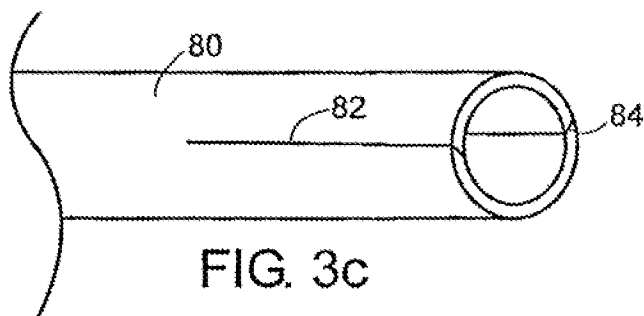


FIG. 3c

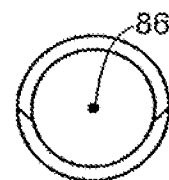


FIG. 3d

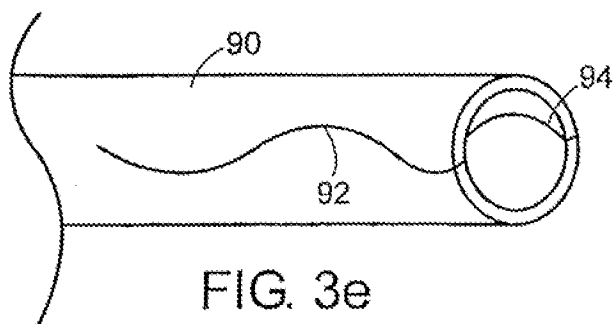


FIG. 3e

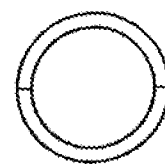


FIG. 3f

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